

Exhibit C

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL 2327 JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
THIS DOCUMENT RELATES TO: <i>Wave 8 Cases</i>	

GENERAL EXPERT REPORT OF RICHARD MARCUS ELLERKMANN, M.D.

Richard Marcus Ellerkmann, M.D. Expert Report on Prolift / Gynemesh PS

Credentials, Experience and Qualifications:

I am board certified in obstetrics and gynecology and female pelvic medicine and reconstructive surgery and I am a Fellow of the American Board of Obstetrics and Gynecology. I currently serve as the Director of the Urogynecology Center at Mercy in Baltimore and I am an Assistant Professor in Obstetrics and Gynecology, Section of Urogynecology and Reconstructive Pelvic Surgery, at Johns Hopkins School of Medicine. Prior to my current position, between 2001 to 2011, I served in various positions at the Greater Baltimore Medical Center/Johns Hopkins Hospital including as the Chief of the Urogynecology, as Interim Chairman of the Department of Gynecology, and as the Associate Fellowship Director for the Division of Urogynecology and Reconstructive Pelvic Surgery at the Greater Baltimore Medical Center as well as the Associate Residency Program Director in Obstetrics and Gynecology at Johns Hopkins Hospital. I am licensed to practice medicine in Maryland.

As set forth on my CV which is attached, I completed my premedical education at Bryn Mawr College in Pennsylvania (1990). I completed my medical school at Dartmouth Medical School, Hanover, New Hampshire in 1994. I followed medical school directly with a four-year residency training program in Obstetrics and Gynecology at Maine Medical Center which I completed in 1998. In 2001, I completed a three-year Fellowship in Urogynecology and Reconstructive Pelvic Surgery at Greater Baltimore Medical Center/ Johns Hopkins Medicine in Baltimore, MD. From 2004 until 2008, I served on the board of the American Urogynecological Society.

I have performed the full range of gynecologic and urogynecologic surgeries over the past 20 years. I have performed various native tissue and mesh augmented surgeries for the treatment of pelvic organ prolapse and stress urinary incontinence. These are two of the most common conditions that I evaluate and treat in patients. I also evaluate and treat patients for a full spectrum of pelvic floor disorders including sexual dysfunction, pelvic pain and dyspareunia, interstitial cystitis, recurrent urinary tract infections, fecal

incontinence, overactive bladder, pelvic floor dysfunction and the special gynecologic needs of aging and handicapped women.

I have been utilizing the TVT device to treat stress urinary incontinence in my patients beginning in 1999. I have also utilized TVT-O, TVT Secur and TVT Exact devices and estimate that I have performed over 1,000 surgeries with the TVT devices during my career. I have also utilized Gynemesh PS, Prolift, and Prolift +M for the treatment of pelvic organ prolapse in hundreds of patients including placement during sacrocolpopexy and transvaginally.

I became an Ethicon preceptor for TVT in 2000, teaching the indications, surgical technique and potential benefits and risks related to this device to other pelvic surgeons. I have completed training in the United States and in Belgium. I have undergone Ethicon sponsored professional education on incontinence and prolapse devices and I have trained other surgeons on patient selection and correct surgical techniques for TVT, TVT-O, and Gynemesh PS/ Prolift including didactic lectures, telesurgery, and cadaver labs since 2000.

In my roles as Chief and Director of various residency and urogynecology fellowship programs, I am familiar with national standards and experienced in the curriculum as set forth in the U.S. for pelvic surgeons. In this role, I have trained pelvic surgeons in the use of midurethral slings such as TVT and TVT-O and the use of transvaginal and abdominal/laparoscopic placement of mesh such as Gynemesh and Prolift to treat prolapse, as well as native tissue repairs. I am also knowledgeable with regard to the national and international use of the various non-mesh and mesh based repairs of these conditions as a result of my roles in various professional societies, my attendance at national and international conferences, my work with national and international pelvic surgeons, and my review of the medical literature.

I have published book chapters, peer reviewed papers and abstracts on various gynecologic and urogynecologic subjects and medical devices. I have also presented on numerous subjects relative to gynecology and urogynecology. My publications and presentations include such subjects as pregnancy, pelvic anatomy, gynecologic

malignancy, gynecologic surgery such as hysterectomy, diagnostic procedures such as urodynamics and MRI, prolapse and stress urinary incontinence, including epidemiology, diagnosis, treatment as well as vaginal, abdominal and laparoscopic surgeries with and without mesh and their techniques, outcomes, and complications, and complication management.

For example, my publications include studies assessing the TVT device and the largest randomized controlled trial comparing a standard retropubic midurethral sling to a mini-sling (TVT versus TVT Secur) where we showed that based on Level 1 evidence in this multi-center study, TVT was efficacious, improved incontinence symptoms, could be quickly and easily performed, and that complication and reoperation rates were low, including a 0.9% rate of mesh exposure and a 2.4% rate of sling release/urethrolysis for the TVT.¹ I have also published a study which shows that gynecologists, urologists, and urogynecologists can quickly and safely perform SUI surgery with the TVT and TVT-O devices, that they are efficacious, that complication and reoperation rates are low, and that there is no difference in operative time, bleeding, perioperative complications, postoperative complications or sling release/excision among the groups.² I have also published on the use of mesh such as Gynemesh PS to treat pelvic organ prolapse.

I have lectured both nationally and internationally on urogynecology topics and worked with US and international pelvic surgeons on issues pertinent to urogynecology. I am a member of numerous professional societies including ACOG, SGS and AUGS and have served in leadership roles including, as noted previously, serving on the Board of Trustees for AUGS.

¹ Barber MD, Ellerkmann M, et al.; Foundation for Female Health Awareness Research Network.. Single-incision mini-sling compared with tension-free vaginal tape for the treatment of stress urinary incontinence: a randomized controlled trial. *Obstet Gynecol.* 2012 Feb;119(2 Pt 1):328-37. PubMed PMID: 22270285.

² Sanses TV, Ellerkmann RM, et al. Outcomes of Retropubic Synthetic Midurethral Gynecare TVT Slings When Performed by Urogynecologists, Urologists, and General Gynecologists in a Private Community Hospital. *Female Pelvic Med Reconstr Surg.* 2010 Jul;16(4):238-41. PubMed PMID: 22453349.

Materials Reviewed:

Materials that I have reviewed and those that I may use at trial including medical records, depositions, medical literature, and device documents are identified either in this report or are listed in the attached Materials List. These include numerous sources such as my education and training, general knowledge, the medical literature, as well as Ethicon documents (Gynemesh PS/ Prolift, TVT, TVT-O IFUs, Surgeons' Monographs, Professional Education Slides pertaining to the devices, etc.), including many of those which I was aware of in my role as a practicing surgeon, my pertinent professional positions, my role as a reviewer for journal manuscripts, my authorship, my role as an educator and teacher to residents and fellows, and as an Ethicon preceptee and proctor/preceptor.

Expert Compensation:

My rates charged for expert work are \$450 per hour for case review and testimony. In the past four years I have given expert testimony in: Jessica Stanley et al vs. Nnamdi Davis, M.D. (Circuit Court St. Mary's County, MD July 13, 2018).

Opinions:

This report contains my opinions that I have formed to date, the bases for those opinions, and the information I considered in forming my opinions. All of my opinions are based on my education, training, clinical experience, the pertinent medical literature, discussions with colleagues, and other materials I have reviewed. All of the opinions I express in this report are held to a reasonable degree of medical and scientific certainty. If I receive additional information after signing this report but before trial, I may form additional or different opinions. I may use the materials identified either in this report and listed in the attached reliance list at trial.

Stress urinary incontinence and pelvic organ prolapse are common conditions in women and cause burdensome symptoms, adverse effects on quality of life, and can interfere with daily activities, relationships, social and sexual function.³ I published on a group of 237 women with prolapse of whom 73 % reported urinary incontinence, 86 % reported urinary urgency and/or frequency, 34–62 % reported voiding dysfunction and 31 % complained of fecal incontinence.⁴ In addition, as discussed later, pain, dyspareunia and sexual dysfunction are commonly seen in patients before pelvic surgery. Indeed, in my study, pelvic pain was reported in 44% of women. Of those experiencing some degree of pain, 69% reported that the pain interfered with their quality of life and 60% considered their pain to be getting worse. 69% (72/105 women) reported dyspareunia (45 women with penile insertion and 62 women with deep penetration). 57% (60/105 women) reported that dyspareunia had adversely affected their frequency of intercourse. Other factors that adversely affected sexual relations to some degree in sexually active patients in my study included fecal incontinence (15%), urinary incontinence (27%), pelvic organ prolapse (28%), spousal limitations (37%), and pelvic pain (41%). As can be seen from my study and other data, prolapse and stress urinary incontinence frequently co-exist and are burdensome to women. Rates of POP and SUI have risen over the decades and it is estimated that about 20% of women will undergo surgery for the correction of POP or SUI in their lifetime.⁵ Thus a standardized, efficacious, reproducible and less morbid approach was needed to treat these conditions and avoid the morbidity with the abdominal approach and the poor efficacy seen with native tissue repairs for POP and SUI. This led to the use of transvaginal mesh to augment pelvic reconstruction surgery.

Prolift is a device designed by pelvic surgeons over many years to treat the various types of prolapse and is composed of Gynemesh PS, a type 1, macroporous mesh knitted with Prolene polypropylene fibers, trocars, cannulae, and retrieval lines all which allow easier

³ Barber MD, Maher C. Epidemiology and outcome assessment of pelvic organ prolapse. *Int Urogynecol J*. 2013 Nov;24(11):1783-90. PubMed PMID: 24142054.

⁴ Ellerkmann RM, et al. Correlation of symptoms with location and severity of pelvic organ prolapse. *Am J Obstet Gynecol*. 2001 Dec;185(6):1332-7. PubMed PMID: 11744905.

⁵ Wu JM, et al. Lifetime risk of stress urinary incontinence or pelvic organ prolapse surgery. *Obstet Gynecol*. 2014 Jun;123(6):1201-6. PubMed PMID: 24807341.

and safer anatomic placement of the mesh in the vesico and rectovaginal space.⁶

Gynemesh PS has large pores, approximately 2.5mm, which allow tissue ingrowth and support of the prolapsed organs. Gynemesh PS in 2002 and Prolift in 2005 followed the use of the macroporous, type 1 Prolene mesh used in the TVT sling in the later 1990s and which had shown significant efficacy, safety and biocompatibility, desirability and benefits in a variety of studies in different cohorts and randomized controlled trials with follow up out to 17 years as discussed later.⁷

As noted in the IFU, Prolift is indicated for tissue reinforcement and long-lasting stabilization of fascial structures of the pelvic floor in vaginal wall prolapse. The device is contraindicated in infants, children, pregnant women and women who are planning future pregnancies. Placement of Gynemesh PS is made in the same planes located

⁶ Debodinance P, et al. [Changing attitudes on the surgical treatment of urogenital prolapse: birth of the tension-free vaginal mesh]. *J Gynecol Obstet Biol Reprod (Paris)*. 2004 Nov;33(7):577-88. PubMed PMID: 15550876.

⁷ Ulmsten U, et al. An ambulatory surgical procedure under local anesthesia for treatment of female urinary incontinence. *Int Urogynecol J Pelvic Floor Dysfunct*. 1996;7(2):81-5; discussion 85-6. PubMed PMID: 8798092; 2001 TVT Surgeons' Resource Monograph; Rezapour M, et al. Tension-Free vaginal tape (TVT) in stress incontinent women with intrinsic sphincter deficiency (ISD)--a long-term follow-up. *Int Urogynecol J Pelvic Floor Dysfunct*. 2001;12 Suppl 2:S12-14. PubMed PMID: 11450973; Rezapour M, Ulmsten U. Tension-Free vaginal tape (TVT) in women with mixed urinary incontinence--a long-term follow-up. *Int Urogynecol J Pelvic Floor Dysfunct*. 2001;12 Suppl 2:S15-18. PubMed PMID: 11450974; Falconer C, et al. Influence of different sling materials on connective tissue metabolism in stress urinary incontinent women. *Int Urogynecol J Pelvic Floor Dysfunct*. 2001;12 Suppl 2:S19-23. PubMed PMID: 11450975; Rezapour M, Ulmsten U. Tension-Free vaginal tape (TVT) in women with recurrent stress urinary incontinence--a long-term follow up. *Int Urogynecol J Pelvic Floor Dysfunct*. 2001;12 Suppl 2:S9-11. PubMed PMID: 11450980; Nilsson CG, Kuuva N. The tension-free vaginal tape procedure is successful in the majority of women with indications for surgical treatment of urinary stress incontinence. *BJOG*. 2001 Apr;108(4):414-9. PubMed PMID: 11305550; Tamussino KF, et al; Austrian Urogynecology Working Group.. Tension-free vaginal tape operation: results of the Austrian registry. *Obstet Gynecol*. 2001 Nov;98(5 Pt 1):732-6. PubMed PMID: 11704161; Kuuva N, Nilsson CG. A nationwide analysis of complications associated with the tension-free vaginal tape (TVT) procedure. *Acta Obstet Gynecol Scand*. 2002 Jan;81(1):72-7. PubMed PMID: 11942891; Ward K, Hilton P; United Kingdom and Ireland Tension-free Vaginal Tape Trial Group.. Prospective multicentre randomised trial of tension-free vaginal tape and colposuspension as primary treatment for stress incontinence. *BMJ*. 2002 Jul 13;325(7355):67. PubMed PMID: 12114234; Lukacz ES, et al. The effects of the tension-free vaginal tape on proximal urethral position: a prospective, longitudinal evaluation. *Int Urogynecol J Pelvic Floor Dysfunct*. 2003 Aug;14(3):179-84. PubMed PMID: 12955339; Dietz HP, et al. Mechanical properties of urogynecologic implant materials. *Int Urogynecol J Pelvic Floor Dysfunct*. 2003 Oct;14(4):239-43. PubMed PMID: 14530834; Paraiso MF, Walters MD, Karram MM, Barber MD. Laparoscopic Burch colposuspension versus tension-free vaginal tape: a randomized trial. *Obstet Gynecol*. 2004 Dec;104(6):1249-58. PubMed PMID: 15572485; Nilsson CG, Falconer C, Rezapour M. Seven-year follow-up of the tension-free vaginal tape procedure for treatment of urinary incontinence. *Obstet Gynecol*. 2004 Dec;104(6):1259-62. PubMed PMID: 15572486.

between the vaginal wall and pelvic organs as a sacralcolpopexy which has long been performed with mesh most commonly polypropylene, is also more efficacious than native tissue repairs, and is accomplished via laparotomy or laparoscopically.⁸ The arms of the mesh are passed through well-known pelvic support structures, the arcus tendineus fasciae pelvis (Anterior Prolift) and the sacrospinous ligaments (Posterior Prolift), via specially designed Prolift cannulae which allow smooth and atraumatic passage, decreased drag and tissue tearing, and they allow for mesh adjustment and fixation. The use of a vaginal approach reduces the morbidity of an abdominal approach. The standardized placement of the mesh also allowed further study and the Prolift and Gynemesh PS are the most studied devices of their kind, with over 100 studies reporting on their efficacy and safety.

Use of Prolift and Gynemesh PS has been shown by Level 1 evidence to provide superior anatomic support to prolapsed organs, as well as significant reduction of subjective bulge complaints, and a reduced risk of reoperation for prolapse.⁹ These data show efficacy

⁸ Lane FE. Repair of posthysterectomy vaginal-vault prolapse. *Obstet Gynecol.* 1962 Jul;20:72-7. PubMed PMID: 14462011; Baker KR, et al. Colposacropexy with Prolene mesh. *Surg Gynecol Obstet.* 1990 Jul;171(1):51-4. PubMed PMID: 2193414; Benson JT, et al. Vaginal versus abdominal reconstructive surgery for the treatment of pelvic support defects: a prospective randomized study with long-term outcome evaluation. *Am J Obstet Gynecol.* 1996 Dec;175(6):1418-21. PubMed PMID: 8987919; Iglesia CB, et al. The use of mesh in gynecologic surgery. *Int Urogynecol J Pelvic Floor Dysfunct.* 1997;8(2):105-15. Review. PubMed PMID: 9297599; Schettini M, et al. Abdominal sacral colpopexy with prolene mesh. *Int Urogynecol J Pelvic Floor Dysfunct.* 1999;10(5):295-9. PubMed PMID: 10543337; Nygaard IE, et al.; Pelvic Floor Disorders Network. Abdominal sacrocolpopexy: a comprehensive review. *Obstet Gynecol.* 2004 Oct;104(4):805-23. Review. PubMed PMID: 15458906; Maher C, Feiner B, Baessler K, Schmid C. Surgical management of pelvic organ prolapse in women. *Cochrane Database Syst Rev.* 2013 Apr 30;(4):CD004014. doi: 10.1002/14651858.CD004014.pub5. Review. Update in: *Cochrane Database Syst Rev.* 2016 Nov 30;11:CD004014. PubMed PMID: 23633316; Maher C, Feiner B, Baessler K, Christmann-Schmid C, Haya N, Brown J. Surgery for women with apical vaginal prolapse. *Cochrane Database Syst Rev.* 2016 Oct 1;10:CD012376. Review. PubMed PMID: 27696355.

⁹ Maher C, et al. Transvaginal mesh or grafts compared with native tissue repair for vaginal prolapse. *Cochrane Database Syst Rev.* 2016 Feb 9;2:CD012079. PubMed PMID: 26858090; Altman D, et al.; Nordic Transvaginal Mesh Group. Anterior colporrhaphy versus transvaginal mesh for pelvic-organ prolapse. *N Engl J Med.* 2011 May 12;364(19):1826-36. Erratum in: *N Engl J Med.* 2013 Jan 24;368(4):394. PubMed PMID: 21561348; Withagen MI, et al. Trocar-guided mesh compared with conventional vaginal repair in recurrent prolapse: a randomized controlled trial. *Obstet Gynecol.* 2011 Feb;117(2 Pt 1):242-50. PubMed PMID: 21252735; Sokol AI, et al. One-year objective and functional outcomes of a randomized clinical trial of vaginal mesh for prolapse. *Am J Obstet Gynecol.* 2012 Jan;206(1):86.e1-9. PubMed PMID: 21974992; El-Nazer MA, et al. Anterior colporrhaphy versus repair with mesh for anterior vaginal wall prolapse: a comparative clinical study. *Arch Gynecol Obstet.* 2012 Oct;286(4):965-72 PubMed PMID: 22648445; Halaska M, et al. A multicenter, randomized, prospective, controlled study comparing sacrospinous fixation and transvaginal mesh in the treatment of

and safety in anterior, posterior and multi-compartment repairs. The mesh was and is state of the art for use in pelvic organ prolapse treatment. There was desirability in the field for a device to provide better support than native tissue repair and Prolift and Gynemesh PS have been shown to do this in the studies. The patients are followed many years after surgery and the studies including long term data show that Prolift and Gynemesh PS provide good durability and anatomic support, significant improvement in prolapse symptoms and quality of life, high levels of patient satisfaction, have an acceptable complication profile, and are safe.¹⁰

posthysterectomy vaginal vault prolapse. *Am J Obstet Gynecol.* 2012 Oct;207(4):301.e1-7. PubMed PMID: 23021692; Svabik K, et al. Comparison of vaginal mesh repair with sacrospinous vaginal colpopexy in the management of vaginal vault prolapse after hysterectomy in patients with levator ani avulsion: a randomized controlled trial. *Ultrasound Obstet Gynecol.* 2014 Apr;43(4):365-71. PubMed PMID: 24615948; Dos Reis Brandão da Silveira S, et al. Multicenter, randomized trial comparing native vaginal tissue repair and synthetic mesh repair for genital prolapse surgical treatment. *Int Urogynecol J.* 2015 Mar;26(3):335-42. PubMed PMID: 25199496; Svabik K, et al. Randomized trial comparing vaginal mesh repair (Prolift Total) versus sacrospinous vaginal colpopexy (SSF) in the management of vaginal vault prolapse after hysterectomy in patients with levator ani avulsion injury – 6 years follow-up. *Int Urogynecol J* 2016; 27(Suppl.1): S59-60.

¹⁰ Lowman JK, et al. Does the Prolift system cause dyspareunia? *Am J Obstet Gynecol.* 2008 Dec;199(6):707.e1-6. PubMed PMID: 18977469; Jacquetin B, Cosson M. Complications of vaginal mesh: our experience. *Int Urogynecol J Pelvic Floor Dysfunct.* 2009 Aug;20(8):893-6. PubMed PMID: 19513574; Huang WC, et al. Outcome of transvaginal pelvic reconstructive surgery with Prolift after a median of 2 years' follow-up. *Int Urogynecol J.* 2011 Feb;22(2):197-203. PubMed PMID: 20821308; Miller D, et al. Prospective clinical assessment of the transvaginal mesh technique for treatment of pelvic organ prolapse- 5-year results. *Female Pelvic Med Reconstr Surg.* 2011 May;17(3):139-43. PubMed PMID: 22453786; de Landsheere L, et al. Surgical intervention after transvaginal Prolift mesh repair: retrospective single-center study including 524 patients with 3 years' median follow-up. *Am J Obstet Gynecol.* 2012 Jan;206(1):83.e1-7. PubMed PMID: 21963098; Chen YS, et al. Midterm prospective comparison of vaginal repair with mesh vs Prolift system devices for prolapse. *Eur J Obstet Gynecol Reprod Biol.* 2012 Oct;164(2):221-6. PubMed PMID: 22771224; Benbouzid S, et al. Pelvic organ prolapse transvaginal repair by the Prolift system: evaluation of efficacy and complications after a 4.5 years follow up. *Int J Urol.* 2012 Nov;19(11):1010-6. PubMed PMID: 22758777; Wang FM, et al. Prospective study of transobturator mesh kit (Prolift™) in pelvic reconstructive surgery with vaginal hysterectomy after 3 years' follow-up. *Arch Gynecol Obstet.* 2013 Aug;288(2):355-9. PubMed PMID: 23435722; Jacquetin B, et al. Total transvaginal mesh (TVM) technique for treatment of pelvic organ prolapse: a 5-year prospective follow-up study. *Int Urogynecol J.* 2013 Oct;24(10):1679-86. PubMed PMID: 23563891; Khan ZA, et al. Outcomes and complications of trans-vaginal mesh repair using the Prolift™ kit for pelvic organ prolapse at 4 years median follow-up in a tertiary referral centre. *Arch Gynecol Obstet.* 2014 Dec;290(6):1151-7. PubMed PMID: 24981047; Svabik K, et al. Randomized trial comparing vaginal mesh repair (Prolift Total) versus sacrospinous vaginal colpopexy (SSF) in the management of vaginal vault prolapse after hysterectomy in patients with levator ani avulsion injury – 6 years follow-up. *Int Urogynecol J* 2016; 27(Suppl.1): S59-60; Meyer I, et al. Synthetic Graft Augmentation in Vaginal Prolapse Surgery: Long-Term Objective and Subjective Outcomes. *J Minim Invasive Gynecol.* 2016 May-Jun;23(4):614-21. PubMed PMID: 26922879; Song W, et al. Anatomical and Functional Outcomes of Prolift Transvaginal Mesh for Treatment of Pelvic Organ Prolapse. *Low Urin Tract Symptoms.* 2016 Sep;8(3):159-64. PubMed PMID: 27619780; Santos F, et al. Transvaginal repair of genital prolapse with Prolift™ system: complications and outcomes after 6

Mesh exposure is a form of wound complication and it has been extensively warned of and reported in the medical literature as discussed below. Mesh exposure/erosion is not from a defect in the device. Mesh exposure can be caused by vaginal atrophy, use of corticosteroids, hypertension, obesity, smoking and other factors which have been associated with poor wound healing^{11, 12}. Further, wound complications occur regardless of whether mesh is used (mesh exposure/erosion) or a native tissue repair is performed (suture exposure/erosion) and the rates seen with these wound complications following native tissue repair are similar and higher to the rates seen with Prolift. For example it has been reported that suture erosion and wound dehiscence occurred in 31.3% of patients undergoing native tissue prolapse repair with permanent sutures, 9% with absorbable sutures, and 16.1% of women with permanent sutures had additional surgical intervention.¹³ Another study involving native tissue prolapse surgery reported that suture-related complications presented at a mean follow up of 19 months in 36% of patients, 74% of the patients had vaginal bleeding, and 70% of patients with symptoms required suture removal.¹⁴ Similarly, another study in native tissue prolapse repair reported suture-related complications presented at a mean follow up of 10.4 months in 45% of patients including a 36% rate of suture exposure, and the authors also reported

years of use – a single-center study. *Eur J Obstet Gynecol Reprod Biol.* 2016; 206: e102; Lo TS, et al. A 52-month follow-up on the transvaginal mesh surgery in vaginal cuff eversion. *Taiwan J Obstet Gynecol.* 2017 Jun;56(3):346-352. PubMed PMID: 28600046; Kraus P, et al. The results of five years follow-up prospective study of vaginal prolapse repaired by prolift total mesh surgery or sacrospinous fixation. *Ceska Gynekol.* 2017 Fall;82(4):277-286. PubMed PMID: 28925271; Ubertazzi EP, et al. Long-term outcomes of transvaginal mesh (TVM) In patients with pelvic organ prolapse: A 5-year follow-up. *Eur J Obstet Gynecol Reprod Biol.* 2018 Apr 14;225:90-94. PubMed PMID: 29680466; Luo DY, et al. Long term (8-year) Follow-up of Transvaginal Anatomical Implant of Mesh in Pelvic organ prolapse. *Sci Rep.* 2018 Feb 12;8(1):2829. doi: 10.1038/s41598-018-21090-w. PubMed PMID: 29434209

¹¹ Tahkin DP, et al. Skin manifestations of inhaled corticosteroids in COPD patients: results from Lung Study II. *Chest* 2004 Oct; 126(4):1123-33.

¹² ACOG Committee Opinion, Gynecologic Surgery in the Obese Women. No. 619, January 2015.

¹³ Luck AM, et al. Suture erosion and wound dehiscence with permanent versus absorbable suture in reconstructive posterior vaginal surgery. *Am J Obstet Gynecol.* 2005 May;192(5):1626-9. PubMed PMID: 15902168.

¹⁴ Toglia MR, Fagan MJ. Suture erosion rates and long-term surgical outcomes in patients undergoing sacrospinous ligament suspension with braided polyester suture. *Am J Obstet Gynecol.* 2008 May;198(5):600.e1-4. PubMed PMID: 18455545.

that vaginal bleeding and suture removal was common.¹⁵ In addition, other complications were reported including cuff abscess, transfusion, fever, buttock pain, leg numbness and ureteral kinking. In a randomized controlled trial that tracked suture and mesh exposure/erosion in patients undergoing native tissue prolapse repair versus the use of Prolift, both patient groups had rates of 15%.¹⁶ The OPTIMAL randomized trial tracked the rates of wound complications following two native tissue prolapse repairs – the uterosacral ligament suspension (ULS) and the sacrospinous ligament fixation (SSLF) – and the authors reported that at two (2) year follow up, there were similar rates of suture exposure 18.4% versus 18.8% and granulation tissue 21.8% versus 14.5%.¹⁷ By five (5) years, the rates were also comparable between the groups – 25.8% versus 25.7% for suture exposure and 28.9% versus 18.8% for granulation tissue. As can be seen the rates following native tissue repair are similar and higher to the rates seen with Prolift.

Dyspareunia and pain are common findings in women with studies reporting $\geq 40\%$ having dyspareunia and/or pelvic pain and $\geq 20\%$ having chronic dyspareunia and/or pelvic pain.¹⁸ Pelvic organ prolapse is well known to frequently lead to sexual dysfunction and pain with intercourse at baseline in up to and over 40% of patients as shown in the earlier studies cited which documented preexisting dyspareunia and sexual function/dysfunction.¹⁹ As discussed earlier, in my study on a group of 237 women,

¹⁵ Yazdany T, et al. Suture complications in a teaching institution among patients undergoing uterosacral ligament suspension with permanent braided suture. *Int Urogynecol J*. 2010 Jul;21(7):813-8. PubMed PMID: 20186391

¹⁶ Sokol AI, Iglesia CB, Kudish BI, Gutman RE, Shveiky D, Bercik R, Sokol ER. One-year objective and functional outcomes of a randomized clinical trial of vaginal mesh for prolapse. *Am J Obstet Gynecol*. 2012 Jan;206(1):86.e1-9. PubMed PMID: 21974992.

¹⁷ Jelovsek JE, et al.; NICHD Pelvic Floor Disorders Network.. Effect of Uterosacral Ligament Suspension vs Sacrospinous Ligament Fixation With or Without Perioperative Behavioral Therapy for Pelvic Organ Vaginal Prolapse on Surgical Outcomes and Prolapse Symptoms at 5 Years in the OPTIMAL Randomized Clinical Trial. *JAMA*. 2018 Apr 17;319(15):1554-1565. PubMed PMID: 29677302

¹⁸ Jamieson DJ, Steege JF. The prevalence of dysmenorrhea, dyspareunia, pelvic pain, and irritable bowel syndrome in primary care practices. *Obstet Gynecol*. 1996 Jan;87(1):55-8. PubMed PMID: 8532266.

¹⁹ Lowman JK, et al. Does the Prolift system cause dyspareunia? *Am J Obstet Gynecol*. 2008 Dec;199(6):707.e1-6. PubMed PMID: 18977469; Dietz V, Maher C. Pelvic organ prolapse and sexual function. *Int Urogynecol J*. 2013 Nov;24(11):1853-7. PubMed PMID: 24142060.

these conditions were very prevalent at baseline.²⁰ Specifically, pelvic pain was reported in 44% of women. Of those experiencing some degree of pain, 69% reported that the pain interfered with their quality of life and 60% considered their pain to be getting worse. 69% (72/105 women) reported dyspareunia (45 women with penile insertion and 62 women with deep penetration). 57% (60/105 women) reported that dyspareunia had adversely affected their frequency of intercourse. Other factors that adversely affected sexual relations to some degree in sexually active patients in my study included fecal incontinence (15%), urinary incontinence (27%), pelvic organ prolapse (28%), spousal limitations (37%), and pelvic pain (41%). Vaginal atrophy is an extremely common cause of pain, dyspareunia and/or an adverse effect on sexual function with rates over 60% reported in women.²¹ Diverticular disease and associated diverticulitis are known etiologies for both chronic and acute abdominal and pelvic pain. Pelvic adhesive disease has been associated with chronic pelvic pain syndromes. It is well substantiated in the medical literature that domestic abuse including sexual and physical abuse by a partner can have life-long adverse psychological consequences, inclusive of post-traumatic stress disorders. A variety of factors can affect a women's sexuality, among them physical disorders, age, psychological factors, depression, an unfulfilling relationship with one's spouse and emotional and physical violence. Domestic violence has been shown to increase the risk of sexual dysfunction, including but not limited to dyspareunia, vulvodynia, vaginismus, diminished libido, impaired orgasm and sexual arousal.²² Mental issues and a history of sexual and physical abuse are thus known to be contributing factors for psychological pain and dyspareunia. Additionally, it is known

²⁰ Ellerkmann RM, et al. Correlation of symptoms with location and severity of pelvic organ prolapse. *Am J Obstet Gynecol*. 2001 Dec;185(6):1332-7. PubMed PMID: 11744905.

²¹ Simon JA, et al. Clarifying Vaginal Atrophy's Impact on Sex and Relationships (CLOSER) survey: emotional and physical impact of vaginal discomfort on North American postmenopausal women and their partners. *Menopause*. 2014 Feb;21(2):137-42. PubMed PMID: 23736862; Minkin MJ, et al. Postmenopausal vaginal atrophy: evaluation of treatment with local estrogen therapy. *Int J Womens Health*. 2014 Mar 12;6:281-8. PubMed PMID: 24648772; Palma F, et al.; Writing group of AGATA study. Vaginal atrophy of women in postmenopause. Results from a multicentric observational study: The AGATA study. *Maturitas*. 2016 Jan;83:40-4. PubMed PMID: 26421474; Krychman M, et al. The Women's EMPOWER Survey: Women's Knowledge and Awareness of Treatment Options for Vulvar and Vaginal Atrophy Remains Inadequate. *J Sex Med*. 2017 Mar;14(3):425-433. PubMed PMID: 28202319.

²² Jamali, S, et al. The impact of intimate male partner violence on women's sexual dysfunction. *J Clin Diagn Res*. 2016 Dec; 10(12): QC29-QC33. PMID 28208946

that sexual well-being frequently declines following the menopause transition and can be associated with significant personal and relationship distress.²³ Disuse atrophy resulting from abstinence from sexual intercourse, especially in post-menopausal women, can result in loss of vaginal elasticity and caliber with resulting dyspareunia when intercourse is first attempted. Thus, dyspareunia, pain and sexual dysfunction are due to numerous other causes as well as issues with the partner, so assuming that pain or dyspareunia are due to Prolift or the Gynemesh PS mesh is speculative and non-evidence based.

As can also be seen from those studies and others, dyspareunia, pain and other complications occurs at similar and higher rates following native tissue prolapse repair. For example, 39% of patients were found to have severe dyspareunia after anterior colporrhaphy in a randomized controlled trial.²⁴ Another study that followed patients after posterior native tissue repair reported that at a mean follow up of 42.5 months, 22% had post-operative vaginal pain, 16% had de novo sexual dysfunction, and additionally, sexual dysfunction increased from 18% to 27% over time.²⁵ Another study in patients undergoing posterior native tissue prolapse surgery reported that 22% had vaginal tightness or sexual dysfunction at follow up and 17% also complained of persistent rectal pain.²⁶ Pain, dyspareunia, and vaginal shortening also occur after hysterectomy.²⁷

The overall data and these comparative studies show that Prolift and the use of Gynemesh PS is not defective, does not lead to a significant increased risk of post-operative

²³ Simon JA, et al. Sexual well-being after menopause: An International Menopause Society White Paper. *Climacteric*. 2018 Jul 10;1-13. PubMed PMID: 29987939.

²⁴ Colombo M, et al. Randomised comparison of Burch colposuspension versus anterior colporrhaphy in women with stress urinary incontinence and anterior vaginal wall prolapse. *BJOG*. 2000 Apr;107(4):544-51. PubMed PMID: 10759276

²⁵ Kahn MA, Stanton SL. Posterior colporrhaphy: its effects on bowel and sexual function. *Br J Obstet Gynaecol*. 1997 Jan;104(1):82-6. PubMed PMID: 8988702.

²⁶ Arnold MW, et al. Rectocele repair. Four years' experience. *Dis Colon Rectum*. 1990 Aug;33(8):684-7. PubMed PMID: 2376225.

²⁷ Abdelmonem AM. Vaginal length and incidence of dyspareunia after total abdominal versus vaginal hysterectomy. *Eur J Obstet Gynecol Reprod Biol*. 2010 Aug;151(2):190-2. PubMed PMID: 20427116; Ercan Ö, et al. Comparison of postoperative vaginal length and sexual function after abdominal, vaginal, and laparoscopic hysterectomy. *Int J Gynaecol Obstet*. 2016 Jan;132(1):39-41. PubMed PMID: 26475076.

dyspareunia, de novo dyspareunia or pain, an adverse change in sexual function as assessed by validated PISQ, or changes in vaginal length or caliber, and many patients see resolution or improvement in baseline pain and dyspareunia and improvement in sexual function.²⁸ Moreover, as discussed later, these claimed injuries have long been warned of in our professional education and training, the medical literature, and Ethicon publications such as Surgeon Monographs, IFUs, and/or Professional Education materials, and are expected to be within the common knowledge of gynecologists and trained pelvic surgeons practicing and performing mesh and non-mesh based FPMRS surgery.

Slings have long been used to treat stress urinary incontinence. In the 1960s surgeons began using synthetic mesh in these slings and in the coming decades this use increased.²⁹ TVT was developed over many years and brought the concept of

²⁸ Dietz V, Maher C. Pelvic organ prolapse and sexual function. *Int Urogynecol J*. 2013 Nov;24(11):1853-7. PubMed PMID: 24142060; Maher C, et al. Transvaginal mesh or grafts compared with native tissue repair for vaginal prolapse. *Cochrane Database Syst Rev*. 2016 Feb 9;2:CD012079. PubMed PMID: 26858090; Schimpf MO, et al.; Society of Gynecologic Surgeons Systematic Review Group.. Graft and Mesh Use in Transvaginal Prolapse Repair: A Systematic Review. *Obstet Gynecol*. 2016 Jul;128(1):81-91. PubMed PMID: 27275813; Altman D, et al.; Nordic Transvaginal Mesh Group. Anterior colporrhaphy versus transvaginal mesh for pelvic-organ prolapse. *N Engl J Med*. 2011 May 12;364(19):1826-36. Erratum in: *N Engl J Med*. 2013 Jan 24;368(4):394. PubMed PMID: 21561348; Withagen MI, et al. Trocar-guided mesh compared with conventional vaginal repair in recurrent prolapse: a randomized controlled trial. *Obstet Gynecol*. 2011 Feb;117(2 Pt 1):242-50. PubMed PMID: 21252735; Sokol AI, et al. One-year objective and functional outcomes of a randomized clinical trial of vaginal mesh for prolapse. *Am J Obstet Gynecol*. 2012 Jan;206(1):86.e1-9. PubMed PMID: 21974992; El-Nazer MA, et al. Anterior colporrhaphy versus repair with mesh for anterior vaginal wall prolapse: a comparative clinical study. *Arch Gynecol Obstet*. 2012 Oct;286(4):965-72 PubMed PMID: 22648445; Halaska M, et al. A multicenter, randomized, prospective, controlled study comparing sacrospinous fixation and transvaginal mesh in the treatment of posthysterectomy vaginal vault prolapse. *Am J Obstet Gynecol*. 2012 Oct;207(4):301.e1-7. PubMed PMID: 23021692; Svabik K, et al. Comparison of vaginal mesh repair with sacrospinous vaginal colpopexy in the management of vaginal vault prolapse after hysterectomy in patients with levator ani avulsion: a randomized controlled trial. *Ultrasound Obstet Gynecol*. 2014 Apr;43(4):365-71. PubMed PMID: 24615948; Dos Reis Brandão da Silveira S, et al. Multicenter, randomized trial comparing native vaginal tissue repair and synthetic mesh repair for genital prolapse surgical treatment. *Int Urogynecol J*. 2015 Mar;26(3):335-42. PubMed PMID: 25199496; Svabik K, et al. Randomized trial comparing vaginal mesh repair (Prolift Total) versus sacrospinous vaginal colpopexy (SSF) in the management of vaginal vault prolapse after hysterectomy in patients with levator ani avulsion injury – 6 years follow-up. *Int Urogynecol J* 2016; 27(Supp.1): S59-60.

²⁹ Williams TJ, TeLinde RW. The sling operation for urinary incontinence using mersilene ribbon. *Obstet Gynecol*. 1962 Feb;19:241-5. PubMed PMID: 14007228; Morgan JE. A sling operation, using Marlex polypropylene mesh, for treatment of recurrent stress incontinence. *Am J Obstet Gynecol*. 1970 Feb 1;106(3):369-77. PubMed PMID: 5460696; Horbach NS, et al. A suburethral sling procedure with polytetrafluoroethylene for the treatment of genuine stress incontinence in patients with low urethral closure pressure. *Obstet Gynecol*. 1988 Apr;71(4):648-52. PubMed PMID: 3353056.

midurethral placement of a narrow macroporous tape and its benefits as further discussed. The use of TVT and TVT-O provides excellent treatment of SUI, are safe and effective first line surgical options, and are within the standard of care for the treatment of SUI.³⁰ The TVT and TVT-O devices are highly effective and comparable, which is not surprising as they both use the same Prolene polypropylene tape at the midurethra, and are safer than other SUI options.³¹ TVT-O built upon the critical, revolutionary, and highly desirable design aspects of the TVT, namely a precise, inside first midurethral placement of Prolene polypropylene tape that was not anchored with sutures or bone screws, was efficacious, well tolerated, biocompatible, minimally invasive, easily performed with a short operative time, easily taught, easily studied, reproducible, with low impact on recovery and limitations, with less voiding dysfunction, no need for harvesting tissue leading to those attendant wound complications and scarring flowing from the harvest, and had a positive benefit to risk ratio.³² The further development and

³⁰ Committee on Practice Bulletins—Gynecology and the American Urogynecologic Society. ACOG Practice Bulletin No. 155: Urinary Incontinence in Women. *Obstet Gynecol.* 2015 Nov;126(5):e66-81. PubMed PMID: 26488524; Kobashi KC, et al. Surgical Treatment of Female Stress Urinary Incontinence: AUA/SUFU Guideline. *J Urol.* 2017 Oct;198(4):875-883. PubMed PMID: 28625508.

³¹ Tan PF, et al. Effectiveness and complication rates of tension-free vaginal tape, transobturator tape, and tension-free vaginal tape-obturator in the treatment of female stress urinary incontinence in a medium- to long-term follow up. Meta-analysis of randomized controlled trials. *Saudi Med J.* 2014 Jan;35(1):20-32. PubMed PMID: 24445886; Laurikainen E, et al. Five-year results of a randomized trial comparing retropubic and transobturator midurethral slings for stress incontinence. *Eur Urol.* 2014 Jun;65(6):1109-14. PubMed PMID: 24508070.

³² Petros PE, Ulmsten UI. An integral theory of female urinary incontinence. Experimental and clinical considerations. *Acta Obstet Gynecol Scand Suppl.* 1990;153:7-31. PubMed PMID: 2093278; Ulmsten U, Petros P. Intravaginal slingplasty (IVS): an ambulatory surgical procedure for treatment of female urinary incontinence. *Scand J Urol Nephrol.* 1995 Mar;29(1):75-82. PubMed PMID: 7618052; Ulmsten U, et al. An ambulatory surgical procedure under local anesthesia for treatment of female urinary incontinence. *Int Urogynecol J Pelvic Floor Dysfunct.* 1996;7(2):81-5; discussion 85-6. PubMed PMID: 8798092; Falconer C, et al. Influence of different sling materials on connective tissue metabolism in stress urinary incontinent women. *Int Urogynecol J Pelvic Floor Dysfunct.* 2001;12 Suppl 2:S19-23. PubMed PMID: 11450975; Nilsson CG, et al. Long-term results of the tension-free vaginal tape (TVT) procedure for surgical treatment of female stress urinary incontinence. *Int Urogynecol J Pelvic Floor Dysfunct.* 2001;12 Suppl 2:S5-8. PubMed PMID: 11450979; Petros P. Creating a gold standard surgical device: scientific discoveries leading to TVT and beyond: Ulf Ulmsten Memorial Lecture 2014. *Int Urogynecol J.* 2015 Apr;26(4):471-6. PubMed PMID: 25693655; Nilsson CG. Creating a gold standard surgical procedure: the development and implementation of TVT : Ulf Ulmsten Memorial Lecture 2014. *Int Urogynecol J.* 2015 Jun;26(6):787-9. PubMed PMID: 25731721; IUGA Position Statement on Mid-Urethral Slings for Stress Urinary Incontinence. 2014 July 21. https://new.iuga.org/index.php?preview=1&option=com_dropfiles&format=&task=frontfile.download&catid=48&id=6&Itemid=1000000000000

design of the TVT-O allowed for the same direct midurethral placement (inside via a small incision then moving laterally – the inside-out approach) and exit through the obturator space via use of helical trocars and a winged guide to aide in the safe trajectory and passage of the tape avoiding the retropubic space.³³ These design features have great utility and are revolutionary and state of the art in the surgical management of SUI.

Midurethral slings such as TVT and TVT-O are the best and first line surgical option to treat SUI.³⁴ As noted by the AUA following their review of numerous studies on SUI surgery, “Suburethral synthetic polypropylene mesh sling placement is the most common surgery currently performed for SUI. Extensive data exist to support the use of synthetic polypropylene mesh suburethral slings for the treatment of female SUI, with minimal morbidity compared with alternative surgeries.”³⁵

TVT and TVT-O are composed of a thin 1.1 cm wide strip of Prolene polypropylene mesh which is a Type 1, macroporous, monofilament mesh and is the most biocompatible tape for SUI surgery.³⁶ Design features of the devices allow for the quick and minimally invasive placement of the sling under the midurethra with minimal effect on recovery. For example, TVT and TVT-O have been shown by Level 1 evidence in the Cochrane

³³ de Leval J. Novel surgical technique for the treatment of female stress urinary incontinence: transobturator vaginal tape inside-out. *Eur Urol.* 2003 Dec;44(6):724-30. PubMed PMID: 14644127; de Leval J, Waltregny D. New surgical technique for treatment of stress urinary incontinence TVT-Obturator: new developments and results. *Surg Technol Int.* 2005;14:212-21. PubMed PMID: 16525975; Bonnet P, et al. Transobturator vaginal tape inside out for the surgical treatment of female stress urinary incontinence: anatomical considerations. *J Urol.* 2005 Apr;173(4):1223-8. PubMed PMID: 15758757; Waltregny D, et al. Inside out transobturator vaginal tape for the treatment of female stress urinary incontinence: interim results of a prospective study after a 1-year minimum followup. *J Urol.* 2006 Jun;175(6):2191-5. PubMed PMID: 16697838; Collinet P, et al. The safety of the inside-out transobturator approach for transvaginal tape (TVT-O) treatment in stress urinary incontinence: French registry data on 984 women. *Int Urogynecol J Pelvic Floor Dysfunct.* 2008 May;19(5):711-5. PubMed PMID: 18197353.

³⁴ AUGS, SUFU, AAGL, ACOG, NAFC, IUGA, SGS Position Statement Mesh Midurethral Slings for Stress Urinary Incontinence. 2018 Feb <http://www.sgsonline.org/assets/docs/AUGS-SUFU%20MUS%20Position%20Statement%20UPDATED%202.2018.pdf>

³⁵ AUA Position Statement on the Use of Vaginal mesh for the Surgical Treatment of SUI. 2013 Oct. <http://www.auanet.org/guidelines/use-of-vaginal-mesh-for-the-surgical-treatment-of-stress-urinary-incontinence>

³⁶ Ford AA, et al. Mid-urethral sling operations for stress urinary incontinence in women. *Cochrane Database Syst Rev.* 2017 Jul 31;7:CD006375. PubMed PMID: 28756647;

Review to have several advantages including shorter operative time/anesthetic need, reduced surgical pain, reduced hospitalization, and reduced voiding dysfunction.³⁷ While mesh-related complications can occur following polypropylene sling placement, the rate of these complications is acceptably low as further discussed.

We have shown that the TVT and TVT-O are easily taught, reproducible and can be performed quickly, easily and safely by gynecologists, urologists and gynecologists.³⁸ In our study, it was shown that sling OR time was 38.8 ± 8.5 minutes for URO-GYN, 42.6 ± 11.2 minutes for URO, and 39.8 ± 14.3 minutes for GYN, $P = 0.30$. Estimated blood loss was 56.6 ± 68.3 mL for URO-GYN, 69.7 ± 82.6 mL for URO, and 68.8 ± 73.4 mL for GYN, $P = 0.37$. The intraoperative complications (bladder, urethral perforations, and hemorrhage) were similar among the specialties. In the postoperative period, complication rates were low and there was no difference in complications including the subsequent need for urethrolisis (cutting or removal of the sling), return to OR, and readmission to the hospital after the procedure among all 3 specialties. As a result, the retropubic and midurethral slings are part of the required curriculum for gynecology, female urology and FPMRS fellowship programs.

Furthermore, many sling-related complications are not unique to mesh surgeries and are known to occur with non-mesh sling procedures as well.³⁹ Voiding dysfunction is a

³⁷ Ogah J, et al. Minimally invasive synthetic suburethral sling operations for stress urinary incontinence in women. *Cochrane Database Syst Rev*. 2009 Oct 7;(4):CD006375. PubMed PMID: 19821363.

³⁸ Sanses TV, Ellerkmann RM, et al. Outcomes of Retropubic Synthetic Midurethral Gynecare TVT Slings When Performed by Urogynecologists, Urologists, and General Gynecologists in a Private Community Hospital. *Female Pelvic Med Reconstr Surg*. 2010 Jul;16(4):238-41. PubMed PMID: 22453349.

³⁹ Alcalay M, et al. Burch colposuspension: a 10-20 year follow up. *Br J Obstet Gynaecol*. 1995 Sep;102(9):740-5. Erratum in: *Br J Obstet Gynaecol* 1996 Mar;103(3):290. PubMed PMID: 7547767; Chaliha C, Stanton SL. Complications of surgery for genuine stress incontinence. *Br J Obstet Gynaecol*. 1999 Dec;106(12):1238-45. PubMed PMID: 10609716; Weber AM, et al. Sexual function and vaginal anatomy in women before and after surgery for pelvic organ prolapse and urinary incontinence. *Am J Obstet Gynecol*. 2000 Jun;182(6):1610-5. PubMed PMID: 10871485; Demirci F, et al. Long-term results of Burch colposuspension. *Gynecol Obstet Invest*. 2001;51(4):243-7. PubMed PMID: 11408735.; Cox A, et al. Surgical management of female SUI: is there a gold standard? *Nat Rev Urol*. 2013 Feb;10(2):78-89. PubMed PMID: 23318365; Kurkijärvi K, et al. Reoperations for Female Stress Urinary Incontinence: A Finnish National Register Study. *Eur Urol Focus*. 2017 Jun 10. PubMed PMID: 28753896.; Kobashi KC, et al. Surgical Treatment of Female Stress Urinary Incontinence: AUA/SUFU Guideline. *J Urol*. 2017 Oct;198(4):875-883. PubMed PMID: 28625508; Schimpf MO, et al.; Society of Gynecologic Surgeons

significant risk for the older repairs for SUI and TVT and TVT-O have reduced this risk. Rates of voiding dysfunction vary from 2%–4% after TVT, 5%–20% following Marshall–Marchetti–Krantz (MMK) procedures, 4%–22% following Burch colposuspension, and the rate with pubovaginal slings has been noted to be among the highest due to its more constrictive effect at the bladder neck.⁴⁰

The risk of wound complications and suture erosion/exposure with alternative SUI surgery such as the Burch colposuspension and autologous and biologic slings are higher.⁴¹ The Burch colposuspension “does carry some morbidity with its incision as shown in the SISTER trial with over 20% of patients having wound related issues.”⁴² The AUA and SUFU have also reported that “patients undergoing autologous fascial sling have the additional risk of possible wound infection, seroma formation, or ventral incisional or leg hernia depending on the fascial harvest site (i.e. rectus fascia versus fascia lata, respectively), and pain at the harvesting site.” 45% of patients who have undergone autologous fascia lata harvest report postoperative discomfort, weakness, lateral thigh bulge, and/or unacceptable incisional cosmesis including 19% with

Systematic Review Group.. Sling surgery for stress urinary incontinence in women: a systematic review and metaanalysis. *Am J Obstet Gynecol*. 2014 Jul;211(1):71.e1-71.e27. PubMed PMID: 24487005.

⁴⁰ Dunn JS Jr, Ellerkmann RM, et al. Voiding dysfunction after surgery for stress incontinence: literature review and survey results. *Int Urogynecol J Pelvic Floor Dysfunct*. 2004 Jan-Feb;15(1):25-31; discussion 31. Epub 2003 Dec 19. PubMed PMID: 14752595; Albo ME, et al.; Urinary Incontinence Treatment Network.. Burch colposuspension versus fascial sling to reduce urinary stress incontinence. *N Engl J Med*. 2007 May 24;356(21):2143-55. Epub 2007 May 21. PubMed PMID: 17517855; Ogah J, et al. Minimally invasive synthetic suburethral sling operations for stress urinary incontinence in women. *Cochrane Database Syst Rev*. 2009 Oct 7;(4):CD006375. PubMed PMID: 19821363.

⁴¹ Athanasopoulos A, et al. Efficacy and preoperative prognostic factors of autologous fascia rectus sling for treatment of female stress urinary incontinence. *Urology*. 2011 Nov;78(5):1034-8. PubMed PMID: 22054371; Albo ME, et al.; Urinary Incontinence Treatment Network. Burch colposuspension versus fascial sling to reduce urinary stress incontinence. *N Engl J Med*. 2007 May 24;356(21):2143-55. Epub 2007 May 21. PubMed PMID: 17517855; Chaliha C, Stanton SL. Complications of surgery for genuine stress incontinence. *Br J Obstet Gynaecol*. 1999 Dec;106(12):1238-45. Review. PubMed PMID: 10609716; Kammerer-Doak DN, et al. Vaginal erosion of cadaveric fascia lata following abdominal sacrocolpopexy and suburethral sling urethropexy. *Int Urogynecol J Pelvic Floor Dysfunct*. 2002;13(2):106-9; discussion 109. PubMed PMID: 12054177; Handa VL, et al. Banked human fascia lata for the suburethral sling procedure: a preliminary report. *Obstet Gynecol*. 1996 Dec;88(6):1045-9. PubMed PMID: 8942851.

⁴² Kobashi KC, et al. Surgical Treatment of Female Stress Urinary Incontinence: AUA/SUFU Guideline. *J Urol*. 2017 Oct;198(4):875-883. PubMed PMID: 28625508;

persistent numbness and 13% with overall dissatisfaction.⁴³ Studies have also shown lower rates of reoperation, prolapse, dyspareunia and less postoperative voiding dysfunction and de novo urgency symptoms, and urge incontinence with TVT/TVT-O compared to Burch colposuspension and autologous slings.⁴⁴

Conversely, the rates of mesh exposure after TVT and TVT-O are in the 0.5% to 2.5% range based on meta-analyses of registry, randomized controlled trials and medium and long term data in over 200,000 patients.⁴⁵ For example, I participated in the assessment of the TVT device in the largest randomized controlled trial comparing a standard retropubic midurethral sling to a mini-sling and had a 0.9% rate of mesh exposure and a 2.4% rate of sling release/urethrolysis for the TVT.⁴⁶ Thus, the risk of wound complications with the Burch and autologous slings are much higher than the rates with TVT and TVT-O. Level 1 systematic reviews and metaanalyses also show that the rates of mesh exposure and vaginal injury with TVT and TVT-O are lower than outside-in transobturator slings.⁴⁷ Similarly the Cochrane Review showed that monofilament tapes

⁴³ Walter AJ, et al. Harvesting autologous fascia lata for pelvic reconstructive surgery: techniques and morbidity. *Am J Obstet Gynecol.* 2001 Dec;185(6):1354-8; discussion 1459. PubMed PMID: 11744909.

⁴⁴ Kurkijärvi K, et al. Reoperations for Female Stress Urinary Incontinence: A Finnish National Register Study. *Eur Urol Focus.* 2017 Jun 10. pii: S2405-4569(17)30123-2. [Epub ahead of print] PubMed PMID: 28753896; Schimpf MO, et al.; Society of Gynecologic Surgeons Systematic Review Group.. Sling surgery for stress urinary incontinence in women: a systematic review and metaanalysis. *Am J Obstet Gynecol.* 2014 Jul;211(1):71.e1-71.e27. PubMed PMID: 24487005; Dmochowski RR, et al.; Female Stress Urinary Incontinence Update Panel of the American Urological Association Education and Research, Inc., Whetter LE. Update of AUA guideline on the surgical management of female stress urinary incontinence. *J Urol.* 2010 May;183(5):1906-14. PubMed PMID: 20303102; Ogah J, et al. Minimally invasive synthetic suburethral sling operations for stress urinary incontinence in women. *Cochrane Database Syst Rev.* 2009 Oct 7;(4):CD006375. PubMed PMID: 19821363.

⁴⁵ Ford AA, et al. Mid-urethral sling operations for stress urinary incontinence in women. *Cochrane Database Syst Rev.* 2015 Jul 1;(7):CD006375. PubMed PMID: 26130017; Tommaselli GA, et al. Medium-term and long-term outcomes following placement of midurethral slings for stress urinary incontinence: a systematic review and metaanalysis. *Int Urogynecol J.* 2015 Sep;26(9):1253-68. PubMed PMID: 25990203; Fusco F, et al. Updated Systematic Review and Meta-analysis of the Comparative Data on Colposuspensions, Pubovaginal Slings, and Midurethral Tapes in the Surgical Treatment of Female Stress Urinary Incontinence. *Eur Urol.* 2017 Oct;72(4):567-591. PubMed PMID: 28479203.

⁴⁶ Barber MD, Ellerkmann M, et al.; Foundation for Female Health Awareness Research Network.. Single-incision mini-sling compared with tension-free vaginal tape for the treatment of stress urinary incontinence: a randomized controlled trial. *Obstet Gynecol.* 2012 Feb;119(2 Pt 1):328-37. PubMed PMID: 22270285.

⁴⁷ Fusco F, et al. Updated Systematic Review and Meta-analysis of the Comparative Data on Colposuspensions, Pubovaginal Slings, and Midurethral Tapes in the Surgical Treatment of Female Stress

such as TVT and TVT-O had significantly higher objective cure rates and fewer tape erosions 1.3% versus 6%, than multifilament tapes.⁴⁸ The overall data show that there is no more effective, safer, less invasive, durable and more studied option than the TVT and TVT-O.

These and other studies document that TVT and TVT-O have been studied in over 100 randomized controlled trials, numerous systematic reviews, metaanalyses, registries, and long term studies and the overall efficacy rate is in the 80-95% range, the devices are durable and desirable for the treatment of SUI, reduce incontinence symptoms, improve quality of life and voiding during intercourse, and have low rates of complications such as voiding dysfunction/retention 1-3% and dyspareunia <1%, and a 1-5% rate of reoperation at long term out to 17 years.⁴⁹

Urinary Incontinence. *Eur Urol.* 2017 Oct;72(4):567-591. PubMed PMID: 28479203; Tommaselli GA, et al. Medium-term and long-term outcomes following placement of midurethral slings for stress urinary incontinence: a systematic review and metaanalysis. *Int Urogynecol J.* 2015 Sep;26(9):1253-68. PubMed PMID: 25990203; Tan PF, et al. Effectiveness and complication rates of tension-free vaginal tape, transobturator tape, and tension-free vaginal tape-obturator in the treatment of female stress urinary incontinence in a medium- to long-term follow up. Meta-analysis of randomized controlled trials. *Saudi Med J.* 2014 Jan;35(1):20-32. PubMed PMID: 24445886.

⁴⁸ Ogah J, et al. Minimally invasive synthetic suburethral sling operations for stress urinary incontinence in women: a short version Cochrane review. *Neurourol Urodyn.* 2011 Mar;30(3):284-91. PubMed PMID: 21412819.

⁴⁹ Nilsson CG, et al. Seventeen years' follow-up of the tension-free vaginal tape procedure for female stress urinary incontinence. *Int Urogynecol J.* 2013 Aug;24(8):1265-9. Epub 2013 Apr 6. PubMed PMID: 23563892; Jonsson Funk M, et al. Sling revision/removal for mesh erosion and urinary retention: long-term risk and predictors. *Am J Obstet Gynecol.* 2013 Jan;208(1):73.e1-7. PubMed PMID: 23099189; Nguyen JN, et al. Perioperative complications and reoperations after incontinence and prolapse surgeries using prosthetic implants. *Obstet Gynecol.* 2012 Mar;119(3):539-46. PubMed PMID: 22353951; Tommaselli GA, et al. Medium-term and long-term outcomes following placement of midurethral slings for stress urinary incontinence: a systematic review and metaanalysis. *Int Urogynecol J.* 2015 Sep;26(9):1253-68. PubMed PMID: 25990203; Unger CA, et al. Indications and risk factors for midurethral sling revision. *Int Urogynecol J.* 2016 Jan;27(1):117-22. PubMed PMID: 26134541; Laurikainen E, et al. Five-year results of a randomized trial comparing retropubic and transobturator midurethral slings for stress incontinence. *Eur Urol.* 2014 Jun;65(6):1109-14. PubMed PMID: 24508070; Kuuva N, Nilsson CG. A nationwide analysis of complications associated with the tension-free vaginal tape (TVT) procedure. *Acta Obstet Gynecol Scand.* 2002 Jan;81(1):72-7. PubMed PMID: 11942891; Tamussino KF, et al.; Austrian Urogynecology Working Group.. Tension-free vaginal tape operation: results of the Austrian registry. *Obstet Gynecol.* 2001 Nov;98(5 Pt 1):732-6. PubMed PMID: 11704161; Tamussino K, et al.; Austrian Urogynecology Working Group.. Transobturator tapes for stress urinary incontinence: Results of the Austrian registry. *Am J Obstet Gynecol.* 2007 Dec;197(6):634.e1-5. PubMed PMID: 18060959; Collinet P, et al. The safety of the inside-out transobturator approach for transvaginal tape (TVT-O) treatment in stress urinary incontinence: French registry data on 984 women. *Int Urogynecol J Pelvic Floor Dysfunct.* 2008 May;19(5):711-5. PubMed PMID: 18197353; Heinonen P, et al. Tension-free vaginal tape procedure

A recent 17 year prospective study showed TVT to have high rates of objective cure 91% and subjective cure 89%, significant durability, low rates of complications including no significant pelvic organ prolapse, de novo dyspareunia, or vaginal, bladder or urethral erosion were recorded, and none of the patients required tape release or resection during the 17 years.⁵⁰ A recent 10 year prospective study showed TVT-O to have high rates of objective cure 92% and subjective cure 97%.⁵¹ A 7.5 year study also showed TVT-O to have high objective and subjective cure rates 82% and 84% and no patients required tape release or resection.⁵² A 5 year study showed that TVT-O had high rates of SUI cure (87% resolved and 92% improved) and improved OAB and urgency symptoms.⁵³ Overall these data show that the TVT and TVT-O are the most studied options with the largest patient cohorts, the longest follow up, and they are effective, durable, safe, highly desirable and useful options for the surgical treatment of SUI.

OAB and urge incontinence are very common in women. It has been reported that “In large epidemiologic studies, the prevalence of OAB symptoms in postmenopausal women, according to the ICS definition, varies between 20% and 40%, increasing with age.”⁵⁴ The studies cited in my report show that TVT and TVT-O is not a cause of OAB

without preoperative urodynamic examination: long-term outcome. *Int J Urol*. 2012 Nov;19(11):1003-9. PubMed PMID: 22725673; Svenningsen R, et al. Long-term follow-up of the retropubic tension-free vaginal tape procedure. *Int Urogynecol J*. 2013 Aug;24(8):1271-8. PubMed PMID: 23417313; Welk B, et al. Removal or Revision of Vaginal Mesh Used for the Treatment of Stress Urinary Incontinence. *JAMA Surg*. 2015 Dec;150(12):1167-75. PubMed PMID: 26352538.

⁵⁰ Braga A, et al. Tension-free vaginal tape for treatment of pure urodynamic stress urinary incontinence: efficacy and adverse effects at 17-year follow-up. *BJU Int*. 2018 Feb 22. [Epub ahead of print] PubMed PMID: 29468798

⁵¹ Serati M, et al. Tension-free Vaginal Tape-Obturator for Treatment of Pure Urodynamic Stress Urinary Incontinence: Efficacy and Adverse Effects at 10-year Follow-up. *Eur Urol*. 2017 Apr;71(4):674-679. PubMed PMID: 27597239.

⁵² Athanasiou S, et al. Seven years of objective and subjective outcomes of transobturator (TVT-O) vaginal tape: why do tapes fail? *Int Urogynecol J*. 2014 Feb;25(2):219-25. PubMed PMID: 23892532.

⁵³ Cheng D, Liu C. Tension-free vaginal tape-obturator in the treatment of stress urinary incontinence: a prospective study with five-year follow-up. *Eur J Obstet Gynecol Reprod Biol*. 2012 Apr;161(2):228-31. PubMed PMID: 22336228.

⁵⁴ Aigmueller T, et al. Ten-year follow-up after the tension-free vaginal tape procedure. *Am J Obstet Gynecol*. 2011 Nov;205(5):496.e1-5. doi: 10.1016/j.ajog.2011.07.010. Epub 2011 Jul 20. PubMed PMID: 21944223 ();

or worsening OAB. In fact the studies show that in many women, their OAB at baseline improves. For example, 84% of women were cured of their preoperative moderate/severe frequency and urgency symptoms and de novo urgency incontinence was experienced by 2.8% of patients in a five year randomized controlled trial involving TVT versus TVT-O.⁵⁵ In another TVT-O study, 76% of patients with preoperative urgency symptoms reported an improvement with a follow up of seven years and de novo urgency was reported in 7 % of patients.⁵⁶ Another study that followed TVT-O patients for five years reported that in addition to high rates of SUI cure (87% resolved and 92% improved), TVT-O significantly improved frequency and urge symptoms, reducing or stopping urinary incontinence and diminishing urine overflow leak in patients with SUI and mixed urinary incontinence.⁵⁷ They observed a significant remission of urge urinary incontinence at both one year (29% vs. 57.3%, $P < 0.001$) and five years (25% vs. 57.3%) after TVT-O. There were also significant patient improvements in the scores of the Short Urinary Distress Inventory (SUDI, $P < 0.05$), Short Incontinence Impact Questionnaire (SIIQ, $P < 0.05$), and health related quality of life (EuroQol, $P < 0.05$) at one and five years. Also, the risk of OAB following TVT and TVT-O is lower than that of other SUI surgeries based on the studies cited in my report.

The claimed injuries and complications at issue such as wound complications such as exposure/erosion, injury to organs and nerves, bleeding and hematoma, voiding problems and retention, pain, dyspareunia and sexual dysfunction, infection, abscess, fistula and sinus formation, UTI, recurrence, surgery to treat complications, etc. have long been warned of in our professional education and training, the medical literature, and Ethicon publications such as Surgeon Monographs, IFUs, and/or Professional Education materials, and are expected to be within the common knowledge of gynecologists, female

⁵⁵ Laurikainen E, et al. Five-year results of a randomized trial comparing retropubic and transobturator midurethral slings for stress incontinence. *Eur Urol*. 2014 Jun;65(6):1109-14. PubMed PMID: 24508070

⁵⁶ Athanasiou S, et al. Seven years of objective and subjective outcomes of transobturator (TVT-O) vaginal tape: why do tapes fail? *Int Urogynecol J*. 2014 Feb;25(2):219-25. doi: 10.1007/s00192-013-2186-8. Epub 2013 Jul 27. PubMed PMID: 23892532

⁵⁷ Cheng D, Liu C. Tension-free vaginal tape-obturator in the treatment of stress urinary incontinence: a prospective study with five-year follow-up. *Eur J Obstet Gynecol Reprod Biol*. 2012 Apr;161(2):228-31. doi: 10.1016/j.ejogrb.2012.01.011. Epub 2012 Feb 13. PubMed PMID: 22336228.

urologists, and trained pelvic surgeons practicing and performing mesh and non-mesh based FPMRS surgery. Over 100 years ago surgeons reported on voiding problems, dyspareunia and sexual dysfunction, and other symptoms attendant to pelvic organ prolapse and warned that following anterior repair, patients could have pain, recurrence, voiding dysfunction / frequency, and chronic urinary tract infections.⁵⁸

In the one of the first reports of transvaginal graft usage to treat prolapse in 1955, the authors used tantalum mesh due to the high recurrence rates that were well known and reported with native tissue repair, and they warned that vaginal discharge, granulation tissue, palpable mesh, mesh exposure and the need to perform mesh excision surgery could occur with the implant, as well as other complications including voiding dysfunction/urgency and frequency, cystitis (UTI), and post-operative incisional infection.⁵⁹ The authors also reported that there were risks of fistula, mesh erosion into an organ such as the bladder or urethra, and stress urinary incontinence following surgery, but none were seen in the group of patients. Similarly, in the first description of the use of mesh to treat prolapse abdominally via sacrocolpopexy in 1962, the author noted that recurrence, impairment of vaginal function, pain, vaginal shortening, and rectal displacement were well reported risks with vaginal prolapse repair.⁶⁰

Moreover, the risks of dyspareunia, pain, scarring, vaginal stenosis, shortening and contraction, and the need to re-operate were also well known and reported in the 1960s to pelvic surgeons.⁶¹ These and other risks were also reported in several studies regarding

⁵⁸ Lowson D. An Operation for Elevation of the Female Bladder in Prolapse or Cystocele. *Br Med J*. 1898 Jul 23;2(1960):232-4. PubMed PMID: 20757975

⁵⁹ Moore J, et al. The use of tantalum mesh in cystocele with critical report of ten cases. *Am J Obstet Gynecol*. 1955 May;69(5):1127-35. PubMed PMID: 14361539

⁶⁰ Lane FE. Repair of posthysterectomy vaginal-vault prolapse. *Obstet Gynecol*. 1962 Jul;20:72-7. PubMed PMID: 14462011.

⁶¹ Francis WJ, Jeffcoate TN. Dyspareunia following vaginal operations. *J Obstet Gynaecol Br Commonw*. 1961 Feb;68:1-10. PubMed PMID: 13701244. ("Apareunia and dyspareunia are well accepted complications of operations which involve incision and suture of the vagina, and are variously explained. Some authorities emphasize the part played by tenderness of scars in the vaginal walls, others consider that shortening of the vagina, especially following vaginal hysterectomy, is an important factor. But the most obvious cause for post-operative dyspareunia is narrowing of the introitus and the vagina which results from removal of tissue as part of the cure of prolapse.")

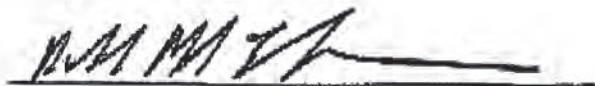
the use of mesh for slings to treat SUI in the 1960s, 1970s and 1980s.⁶² For example, authors studying the use of mesh as a sling to treat SUI reported on outcomes, complications and reoperation and warned that failure, reoperation, wound complications / erosion / seroma, graft and foreign body infection and rejection, sinus tract formation, voiding dysfunction and retention and suprapubic catheter usage, urinary urgency and frequency, persistent detrusor instability, surgical exploration, sling division/revision and removal, urethral irritation/erosion/necrosis, and urinary tract infections including recurrent UTI could occur.⁶³ In 1997, a review titled “The Use of Mesh in Gynecologic Surgery” warned of these well reported and known risks to pelvic surgeons such as mesh exposure/erosion, pain, dyspareunia, voiding difficulties, retention, UTIs and urgency, scarring, infection and rejection, bleeding, injury to organs, vessels and nerves, recurrence, and the need to reoperate for these complications.⁶⁴ These risks are attendant as shown in the literature whether mesh is used or not, are elemental to vaginal and FPMRS surgery, and are part of the basic knowledge expected of the pelvic surgeon in light of their education, training, professional experience, the board certification processes and the medical literature. These risks were extensively reported prior to surgery here. In addition, the Gynemesh/Prolift and TVT/TVT-O Professional education, Surgeons’ Monographs, and IFUs also warned of the pertinent risks given the expected common knowledge of the pelvic surgeon. These materials are clear, helpful and more than adequate to pelvic surgeons. As stated in the IFUs, these devices are intended for pelvic surgeons experienced in POP and SUI repair and the use of mesh for these conditions. The IFU is not a comprehensive text. It concerns general use of the device. Knowledge of benefits, risks, operative techniques, surgical options, complication

⁶² Williams TJ, TeLinde RW. The sling operation for urinary incontinence using mersilene ribbon. *Obstet Gynecol.* 1962 Feb;19:241-5. PubMed PMID: 14007228; Morgan JE. A sling operation, using Marlex polypropylene mesh, for treatment of recurrent stress incontinence. *Am J Obstet Gynecol.* 1970 Feb 1;106(3):369-77. PubMed PMID: 5460696; Stanton SL. Stress incontinence: why and how operations work. *Clin Obstet Gynaecol.* 1985 Jun;12(2):369-77. PubMed PMID: 4040835.

⁶³ Horbach NS, et al. A suburethral sling procedure with polytetrafluoroethylene for the treatment of genuine stress incontinence in patients with low urethral closure pressure. *Obstet Gynecol.* 1988 Apr;71(4):648-52. PubMed PMID: 3353056

⁶⁴ Iglesia CB, et al. The use of mesh in gynecologic surgery. *Int Urogynecol J Pelvic Floor Dysfunct.* 1997;8(2):105-15. Review. PubMed PMID: 9297599

management and how to counsel patients is derived from our medical education, training, textbooks, the medical literature, the conferences we attend, our board certifications and the hospital privilege process. Given the above I find the IFUs informative, helpful and adequate to the pelvic surgeon who would implant the device.

A handwritten signature in black ink, appearing to read 'R. Mark Ellerkmann', written over a horizontal line.

R. Mark Ellerkmann, M.D., F.A.C.O.G
Female Pelvic Medicine and Reconstructive Surgery
Date: August 4, 2018